

ORIGINAL ARTICLE/ARTIGO ORIGINAL/ARTÍCULO ORIGINAL

# CORRELATION BETWEEN QUALITY OF LIFE AND OSTEOLYSIS AROUND LUMBAR PEDICLE SCREWS

RELAÇÃO ENTRE QUALIDADE DE VIDA E OSTEÓLISE EM TORNO DE PARAFUSOS PEDICULARES LOMBARES

CORRELACIÓN ENTRE CALIDAD DE VIDA Y OSTEÓLISIS ALREDEDOR DE TORNILLOS PEDICULARES LUMBARES

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## ABSTRACT

**Objective:** To evaluate whether the presence of osteolysis around the pedicle screws affects the quality of life of patients who underwent posterolateral arthrodesis of the lumbosacral spine. **Methods:** A retrospective study of patients undergoing lumbar posterolateral or lumbosacral arthrodesis due to spinal degenerative disease. CT scans of the operated segments were performed at intervals of 45, 90, 180, and 360 postoperatively. In these tests, the presence of a peri-implant radiolucent halo was investigated, which was considered present when greater than 1mm in the coronal section. Concurrently with the completion of CT scans, the participants completed the questionnaire Oswestry Disability Index (ODI) to assess the degree of disability of the patients. **Results:** A total of 38 patients were evaluated, and 14 (36.84%) of them showed some degree of osteolysis around at least one pedicle screw at the end of follow-up. Of the 242 analyzed screws, 27 (11.15%) had osteolysis in the CT coronal section, with the majority of these occurrences located at the most distal level segment of the arthrodesis. There was no correlation between the presence of the osteolysis to the quality of life of patients. The quality of life has significantly improved when comparing the preoperative results with the postoperative results at different times of application of ODI. This improvement in ODI maintains linearity over time. **Conclusion:** There is no correlation between the presence of peri-implant osteolysis to the quality of life of patients undergoing lumbar or posterolateral lumbosacral arthrodesis in the follow-up period up to 360 days. The quality of life in postoperative has significantly improvement when compared to the preoperative period.

**Keywords:** Osteolysis; Spine fusion; Quality of life; Pseudarthrosis; Spine.

## RESUMO

**Objetivo:** Avaliar se a presença de osteólise em torno dos parafusos pediculares influencia a qualidade de vida de pacientes submetidos à artrodese posterolateral da coluna lombossacral. **Métodos:** Estudo retrospectivo com pacientes submetidos à artrodese posterolateral lombar ou lombossacral por doença espinal degenerativa. Foram realizadas tomografias computadorizadas dos segmentos operados em intervalos de 45, 90, 180 e 360 dias de pós-operatório. Nesses exames, foi pesquisado a presença de um halo radioluciente peri-implante, que foi considerado presente quando maior que 1 mm no corte coronal. Concomitantemente à realização dos exames de TC foi aplicado o questionário Oswestry Disability Index (ODI) para avaliar o grau de incapacidade dos pacientes. **Resultados:** Foram avaliados 38 pacientes e 14 (36,84%) deles apresentavam algum grau de osteólise ao redor de pelo menos um parafuso pedicular ao final do seguimento. Dos 242 parafusos analisados, 27 (11,15%) apresentaram osteólise no corte coronal da TC, sendo a maioria dessas ocorrências no nível mais distal do segmento com artrodese. Não se observou relação da presença dessa osteólise com a qualidade de vida dos pacientes. A qualidade de vida tem melhora significativa quando se compara o resultado pré-operatório com os resultados pós-operatórios nos diversos momentos de aplicação do ODI. Essa melhora no ODI mantém a linearidade de melhora com o passar do tempo. **Conclusão:** Não há relação da presença da osteólise peri-implante com a qualidade de vida dos pacientes submetidos à artrodese lombar ou lombossacral posterolateral no período de seguimento até os 360 dias. A qualidade de vida pós-operatória tem melhora significativa quando comparada ao momento pré-operatório.

**Descritores:** Osteólise; Fusão vertebral; Qualidade de vida; Pseudoartrose; Coluna vertebral.

## RESUMEN

**Objetivo:** Evaluar si la presencia de osteólisis alrededor de los tornillos pediculares afecta la calidad de vida de los pacientes que fueron sometidos a artrodesis posterolateral de la columna lumbosacra. **Métodos:** Estudio retrospectivo de pacientes sometidos a artrodesis lumbar posterolateral o lumbosacra debido a enfermedad degenerativa de la columna vertebral. Se realizaron tomografías computarizadas de los segmentos operados en intervalos de 45, 90, 180 y 360 días después de la cirugía. En estas pruebas, fue investigada la presencia de un halo radiotransparente alrededor del implante, que se consideró presente cuando era mayor que 1 mm en corte coronal. Simultáneamente

Study conducted by the Spine Surgery Group of the Department of Orthopedics and Traumatology of the Faculdade de Ciências Médicas da UNICAMP, Campinas, SP, Brazil.

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con la realización de las tomografías se aplicó el cuestionario Oswestry Disability Index (ODI) para evaluar el grado de discapacidad de los pacientes. Resultados: Se evaluaron 38 pacientes y 14 (36,84%) de ellos tenían algún grado de osteólisis alrededor de al menos un tornillo pedicular al final del seguimiento. De los 242 tornillos analizados, 27 (11,15%) tenían osteólisis en el corte coronal de la tomografía, estando la mayoría de estas ocurrencias, en el nivel más distal de la artrodesis. No hubo correlación entre la presencia de la osteólisis a la calidad de vida de los pacientes. La calidad de vida ha mejorado de manera significativa al comparar los resultados preoperatorios con los resultados postoperatorios en sus distintos momentos del ODI. Esta mejora en el ODI mantiene linealidad de mejoría con el tiempo. Conclusión: No existe correlación entre la presencia de osteólisis alrededor del implante a la calidad de vida de los pacientes sometidos a artrodesis posterolateral lumbar o lumbosacra en el período de seguimiento de hasta 360 días. La calidad de vida postoperatoria ha mejorado significativamente en comparación con el período preoperatorio.

*Descriptores: Osteólisis; Fusión vertebral; Calidad de vida; Seudoartrosis; Columna vertebral.*

## INTRODUCTION

Low back pain or chronic lumbociatalgia, defined as pain lasting more than three months, is the second biggest cause of visits to the doctor and the main cause of absence from work in the USA. It affects 5% to 8% of the general population, and is reported by 19% of the economically active population, generating costs of more than a hundred billion dollars each year.<sup>1,2</sup> There is a wide spectrum of treatments available for patients with chronic low back pain resulting from degenerative changes to the vertebral spine, including conservative and surgical alternatives.<sup>2</sup>

Low back pain and lumbociatalgia are commonly the result of disc disease, which may manifest as intersomatic arthrosis, protrusion and disc extrusion. The degenerative cascade, associated with lesions of the anatomical structures, vertebral instability and narrowing of the canal and intervertebral foramina, generates an environment that could lead to low back pain and radiculopathies.<sup>2,3</sup>

Lumbar arthrodesis has been indicated as one of the treatment alternatives in selected cases of degenerative diseases of the vertebral spine with instability, including scoliosis, spondylolisthesis, and narrowing of the lumbar canal,<sup>2,3</sup> proving efficient, when properly indicated, and resulting in an improvement in the pain and other disabilities generated by these pathologies.<sup>1-4</sup>

Lumbar arthrodeses can be performed via the anterior, posterior, or posterolateral approaches, or a combination of these. The benefits of the posterolateral approach include its relative ease of execution and the fact that most surgeons are familiar with it, the possibility of direct decompression of the neural elements, and the high fusion rates, which are optimized with the use of pedicle instrumentation, increasing the rigidity of the system.<sup>5-9</sup>

Pedicle screw loosening is cited in various studies as one of the complications of vertebral spine surgeries.<sup>10-13</sup> This phenomenon can be observed by the presence of a radiolucent halo, indicating peri-implant osteolysis around the pedicle screw, in the coronal sections of the computed tomography. The presence of this halo is a suggestive sign of pseudoarthrosis.<sup>8,14-16</sup> Its incidence varies between 0.6% and 25%.<sup>8</sup> Schatzker et al.<sup>17</sup> describe the histological finding resulting from micromovements in the bone-implant interface, such as the presence of a fibrous peri-implant tissue, which has a radiological image corresponding to a halo. The sensitivity of the finding of a radiolucent halo for the diagnosis of pseudoarthrosis is 93% and the specificity is 92%.<sup>16</sup> It is known that fusion failure of the arthrodesis can be a source of pain, according to some authors, but there are few reports in the literature, and there is no definitive conclusion as to whether there is a direct relationship between the presence of a radiolucent halo and one of the unfavorable clinical outcomes, such as the presence of postoperative pain.<sup>8,18</sup> Quality of life refers to the dimensions of life that can be affected by diseases or their treatment.<sup>19</sup> It is known that low back pain has a direct negative impact on the patient's quality of life, and that it is a condition commonly associated with severe pain and great physical, social and psychological disability,<sup>20-22</sup> leading to deficits four times greater when compared to the general population, after adjusting for age and comorbidities.<sup>23</sup>

Quality of life questionnaires are a feasible, effective and routinely used tool for monitoring the evolution of patients in treatment with pathologies of the vertebral spine.<sup>24-26</sup> These questionnaires also help

health professionals to evaluate and better understand the patients' expectations and anxieties in the period prior to the proposed treatment, and during the recovery phase.<sup>21</sup> One such questionnaire is the "Oswestry Disability Index" (ODI).<sup>27</sup>

The aim of this study is to evaluate the presence of osteolysis around each of the pedicle screws used in surgical arthrodesis procedures and the time to its occurrence during the first postoperative year, and to correlate this finding with the levels of disability of patients during their evolution, through the application of the ODI.

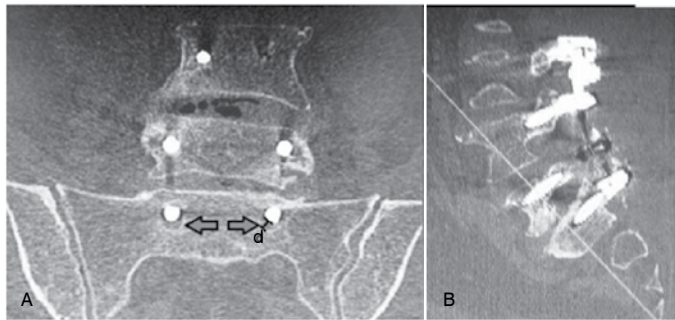
## METHOD

This is a retrospective analysis study of patients submitted to surgical treatment of the vertebral spine, with lumbar or lumbosacral posterolateral arthrodesis instrumented with pedicle screws. The study was conducted from 2010 to 2013 at a tertiary public hospital. Patients aged between 20 and 85 years were included, of both sexes, with a history of degenerative disease of the lumbosacral spine, who had already undergone conservative treatment without improvement in the symptoms. Patients were excluded who had a history of vertebral spine tumor, congenital deformities, a previous history of surgical procedure to the lumbosacral spine, and patients who did not agree to the research terms and did not sign the Informed Consent Form (ICF). The patients responded to the Oswestry Disability Index in the preoperative period, and at 45, 90, 180 and 360 postoperative days. The ODI questionnaire was always applied by an orthopedic surgeon who was trained and familiar with it. The questionnaire consists of 10 questions with six statements in each, to identify limitations when performing nine activities of daily living, and in the patient's sex life. The final score expresses the degree of disability, as a percentage, classifying it as minimal, moderate, severe, very severe and bed-bound or exaggerating the symptoms, as shown in annex 1. At the time of application of the questionnaire, except during the preoperative period, computed tomography exams were taken of the lumbosacral spine. The exams were evaluated by an experienced radiologist who did not have information about the patient's disorders or their clinical information, in order to identify the presence of osteolysis. The observation of a peri-implant radiolucent line greater than 1 mm in the coronal slice of the tomography was considered positive for the presence of osteolysis,<sup>12</sup> as shown in Figure 1. The computed tomography exams were performed using a 64-channel multislice device. Images were used in the coronal and sagittal planes, so that the image in the coronal plane, used for the evaluation of osteolysis, reflected the image of the screw oriented perpendicularly to the vertebra. (Figure 1A) The software Arya Píxeon® version 1.5.5 was used, and sections with thickness of 3 mm.

All the patients agreed to and signed the Informed consent Form (ICF), which was approved by the Institutional Review Board of the Universidade Estadual de Campinas, SP, Brazil, under number 856/2009. For the statistical analysis, the software SPSS 20.0 (SPSS, Inc., Chicago, IL, USA) was used, and a level of significance of 5% was used for the tests.

## RESULTS

The study involved 38 patients; 20 male and 18 female, with a mean age of 51.02 years and median age of 51 years, as shown in Table 1.



**Figure 1.** A and B Example of the measurement of osteolysis in the CT. Coronal section (1 A) perpendicular to the long axis of the screw (1 B). The arrows show the area of osteolysis and the distance "d" is the measurement used to quantify the halo.

**Table 1.** General patient data.

| Variable           | (N = 38)   |
|--------------------|------------|
| <b>Sex, n (%)</b>  |            |
| Female             | 18 (47.4)  |
| Male               | 20 (52.6)  |
| <b>Age (years)</b> |            |
| mean (DP)          | 51 (12.4)  |
| median (min/max)   | 51 (28/84) |

At the end of these 360 days of follow-up, 14 (36.84%) patients presented osteolysis in the computed tomography. The levels of arthrodesis of these patients are shown in Table 2; in the majority of cases, the radiological signal was observed at 90 postoperative days.

A total of 242 screws were evaluated, and osteolysis was found in 27 (11.15%) as shown in Table 3.

The absolute majority of the screws with osteolysis were those of the more distal level of the area of arthrodesis; 12 patients in S1, two patients in L5, and one patient in L2 (this patient also represented osteolysis in the more distal level) as shown in Table 4.

Table 5 presents a comparison between the Oswestry Disability Index score, recorded as a percentage, and the presence of osteolysis in the various evaluation times. It is observed that the levels of disability are very similar in the osteolysis group and the group that did not present this finding.

Looking closely at Table 6, we see that the index of disability presented, on average, difference only between the different evaluation times during the first year of postoperative follow-up, independently of the presence or absence of osteolysis ( $p < 0.001$ ). This finding demonstrates a gradual improvement in the ODI during the evaluation period. The osteolysis did not statistically influence the disability scores of the ODI ( $p=0.559$ ).

Table 7 shows that there is an improvement in the disability index, with statistical significance, when comparing the preoperative result with the other evaluation periods. However, there is no statistical significance when the improvement in ODI is compared among the other evaluation times, in the different postoperative periods.

## DISCUSSION

The use of pedicle screws as a means of stabilization of the spine gained popularity in Europe in the 1980s, through the work of Roy-Camille et al.<sup>28</sup> and became the most prevalent form of spinal fixation in North America in the 1990s. The transpedicle technique enables a rigid, segmental fixation of the vertebral spine under various conditions of spondylolisthesis, tumor, post-traumatic instability, multiple laminectomies, and degenerative arthritis.<sup>10</sup> Despite the efficacy of the pedicle screws used in the treatment of various pathologies of the vertebral spine, it is not free of complications.<sup>14,26,29-31</sup> One of these is loosening of the screw. However, data on this outcome are very varied in the literature, probably due to the different study designs.

McAfee et al.<sup>32</sup> report, in a study of 526 pedicle screws, that there was no loosening. Essens et al.<sup>10</sup> describe a rate of 0.81% of loosening in 617 treated patients. That study also presented a literature review that showed a loosening frequency of between 0.6% and 11%. However, these studies with low screw loosening rates do not describe, in detail, the radiological methods or criteria used to identify the loosening. In three other studies with better detailed radiological methodology, loosening rates of 18%, 21% and 27% were demonstrated.<sup>15,29,33</sup>

Our study showed that of the 242 pedicle screws analyzed, 27 (11.15%) presented signs of loosening, as shown by the tomographic finding of a radiolucent halo larger than 1 mm in the coronal section, described here as osteolysis. These data coincide with the averages described in the literature on the theme. The fact that the highest

**Table 2.** Patients with osteolysis in up to 360 days of follow-up.

|            | Levels submitted to arthrodesis | Level(s) with osteolysis |
|------------|---------------------------------|--------------------------|
| Patient 1  | L3-S1                           | S1                       |
| Patient 2  | L2-L5                           | L5                       |
| Patient 3  | L4-S1                           | S1                       |
| Patient 4  | L1-S1                           | S1                       |
| Patient 5  | L3-S1                           | S1                       |
| Patient 6  | L3-S1                           | S1                       |
| Patient 7  | L3-S1                           | S1                       |
| Patient 8  | L3-S1                           | S1                       |
| Patient 9  | L1-S1                           | S1                       |
| Patient 10 | L4-S1                           | S1                       |
| Patient 11 | L2-S1                           | S1 and L2                |
| Patient 12 | L5-S1                           | S1                       |
| Patient 13 | L3-S1                           | S1                       |
| Patient 14 | L4-L5                           | L5                       |

**Table 3.** Total number of screws evaluated and screws with osteolysis.

|                              |            |
|------------------------------|------------|
| Screws n(%)                  | 242 (100)  |
| Screws with osteolysis n (%) | 27 (11.15) |

**Table 4.** Location of the screws with osteolysis.

|                                    |           |
|------------------------------------|-----------|
| Screws with osteolysis n(%)        | 27 (100)  |
| Screws with osteolysis in S1 n (%) | 20 (74.1) |
| Screws with osteolysis in L5 n (%) | 6 (22.2)  |
| Screws with osteolysis in L2 n (%) | 1 (3.7)   |

**Table 5.** Comparison of ODI with osteolysis in the evaluation times.

| Time (days)  | Osteolysis |      |    |      |      |    |
|--------------|------------|------|----|------|------|----|
|              | No         |      |    | Yes  |      |    |
|              | Mean       | SD   | N  | Mean | SD   | N  |
| Preoperative | 56.4       | 14.9 | 22 | 54.9 | 18.9 | 13 |
| 45           | 25.8       | 23.1 | 22 | 30.4 | 13.8 | 13 |
| 90           | 24.7       | 19.2 | 22 | 32.1 | 17.9 | 14 |
| 180          | 21.3       | 19.1 | 23 | 22.0 | 16.8 | 14 |
| 360          | 17.5       | 15.5 | 23 | 22.4 | 18.8 | 14 |

**Table 6.** Comparison of ODI with osteolysis, evaluation time, and both.

| Variable | Factor              | Test statistic | gl | p      |
|----------|---------------------|----------------|----|--------|
| Oswestry | Osteolysis          | 0.34           | 1  | 0.559  |
|          | Evaluation time     | 133.35         | 4  | <0.001 |
|          | Osteolysis and Time | 4.57           | 4  | 0.334  |

**Table 7.** Comparison of ODI between the various patient evaluation times.

| Variable                         | Time                     | Comparison              | Mean difference or percentage | Standard error | gl | p      | CI (95%) |       |
|----------------------------------|--------------------------|-------------------------|-------------------------------|----------------|----|--------|----------|-------|
|                                  |                          |                         |                               |                |    |        | Lower    | Upper |
| <i>Oswestry Disability Index</i> | All the evaluation times | Preoperative - 45 days  | 28.35                         | 2.77           | 1  | <0.001 | 20.58    | 36.11 |
|                                  |                          | Preoperative - 90 days  | 27.83                         | 3.43           | 1  | <0.001 | 18.21    | 37.44 |
|                                  |                          | Preoperative - 180 days | 33.86                         | 3.79           | 1  | <0.001 | 23.22    | 44.50 |
|                                  |                          | Preoperative - 360 days | 36.07                         | 4.02           | 1  | <0.001 | 24.79    | 47.34 |
|                                  |                          | 45 days - 90 days       | -0.52                         | 2.68           | 1  | >0.999 | -8.04    | 6.99  |
|                                  |                          | 45 days - 180 days      | 5.51                          | 3.40           | 1  | >0.999 | -4.02    | 15.05 |
|                                  |                          | 45 days - 360 days      | 7.72                          | 3.78           | 1  | 0.412  | -2.89    | 18.33 |
|                                  |                          | 90 days - 180 days      | 6.04                          | 2.65           | 1  | 0.228  | -1.41    | 13.48 |
|                                  |                          | 90 days - 360 days      | 8.24                          | 3.37           | 1  | 0.145  | -1.22    | 17.71 |
|                                  |                          | 180 days - 360 days     | 2.21                          | 2.64           | 1  | >0.999 | -5.19    | 9.61  |

incidence of osteolysis was found at the distal level, especially in S1, is explained by the high mechanical demand placed on the lumbosacral junction, a region with biomechanical particularities that make fusion of the arthrodesis difficult, with known high rates of pseudoarthrosis, which is a separate subject of discussion in the field of spinal surgery, as described Harimaya et al.<sup>14</sup>

The aim of our study was to correlate osteolysis of the screws, which represents a sign of instability in the area of arthrodesis, with the quality of life of these patients. It would be expected that patients with this radiological sign of loosening of the implant would present greater pain, resulting in a consequent worsening of the quality of life scores. However, this hypothesis was not confirmed, as the patients without signs of loosening of the implant presented similar quality of life scores to those with this sign. This finding is in accordance with the findings published by Kim et al.<sup>8</sup> who evaluated the prevalence of loosening of the screws and its clinical significance in a study with 24 women submitted to surgery of the vertebral spine due to stenosis. Those authors came to the conclusion that the real significance of the phenomenon of osteolysis is not fully understood, but that it did not have any significance in the clinical evolution of the patient. Wu et al.,<sup>12</sup> in a study with 126 patients and 658 screws analyzed, came to the conclusion that loosening of the screw may be asymptomatic in its presentation, and that it presents an opportunity for bone integration in future follow-up. Tokuhashi et al.<sup>16</sup> concluded that approximately two thirds of the radiolucent zones around the implants disappear with time, and that these are not necessarily diagnostic findings of pseudoarthrosis. On the other hand, it is emphasized that when this zone of radiolucency remains for more than two years after surgery, there is a high risk of the occurrence of pseudoarthrosis.

In this study, we noted an improvement in quality of life in the postoperative period, independently of the presence of osteolysis around the pedicle screws. This improvement in quality of life scores had statistical significance only when the preoperative results were compared with any other postoperative evaluation times. When the quality of life was compared between the different evaluation times in the postoperative period, there was no statistically significant difference.

The improvement in quality of life, measured through the ODI, following a surgical spinal procedure in patients with degenerative disease, is well known in the literature.<sup>26</sup> Carreon et al.<sup>34</sup> in an extensive literature review, showed that patients with degenerative disc disease or spondylolisthesis submitted to surgical treatment had considerable improvements in postoperative ODI. In another study, Carreon et al.<sup>25</sup> observed that patients with worse preoperative ODI scores had more significant improvements during postoperative follow-up.

## CONCLUSION

This study demonstrated that in patients submitted to surgical procedures with posterolateral arthrodesis, using pedicle screws for the treatment of degenerative disease of the vertebral lumbosacral spine, the presence of osteolysis around these pedicle screws did not result in worsening disability in the patients, evaluated by the ODI. Further studies are necessary to understand the real significance of this radiological signal.

All the authors declare no potential conflict of interest concerning this article.

**CONTRIBUTIONS OF THE AUTHORS:** Each author made an individual and significant contribution to the development of the manuscript. MIRN, RR and SMN were the main contributors to the writing of the manuscript. GRZ, IGV and PTMC performed the surgical procedures. MIRN, RR and SMN followed up the patients and gathered clinical data. ACSAF performed the radiological interpretation of the exams. MIRN and GRZ evaluated the data from the statistical analysis. RR, SMN and MIRN carried out the bibliographic review. EL, PTMC, WP, MAT and MIRN reviewed the manuscript and contributed to the intellectual concept of the study.

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#### Annex 1. Presentation of the Oswestry Disability Index.

| Oswestry Disability Index 2.0  |                |
|--|----------------|
| Takes into consideration how far the problem in the back (or legs) has affected the day-to-day activities in the following areas |                |
| 1- intensity of the pain   | 6- standing    |
| 2- personal care   | 7- sleep       |
| 3- lifting heavy objects   | 8- sex life    |
| 4- walking   | 9- social life |
| 5- sitting   | 10- travel     |

| Interpretation of the results of the Oswestry Index |   |
|---|---|
| 0% - 20% :  | minimal disability                      |
| 21% - 40%:  | moderate disability                     |
| 41% - 60%:  | severe disability                       |
| 61% - 80% :   | very severe disability                  |
| 81% - 100%:   | bed-ridden or exaggerating the symptoms |